

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

RANDY J. AFRICANO,

Plaintiff,

v.

ATRIUM MEDICAL CORPORATION,

Defendant.

Case No. 17-cv-7238

Judge Mary M. Rowland

MEMORANDUM OPINION AND ORDER

Plaintiff Randy Africano sues Defendant Atrium Medical Corporation under manufacturing defect and failure-to-warn theories, alleging that Defendant's unsterile mesh injured him after its implantation during inguinal hernia surgery. In advance of the final pretrial conference, the parties have brought various motions in limine. This Court rules below.

LEGAL STANDARD

District courts maintain "broad discretion in ruling on evidentiary questions during trial or before on motions *in limine*." *Jenkins v. Chrysler Motors Corp.*, 316 F.3d 663, 664 (7th Cir. 2002) *see also DiPerna v. Chicago Sch. of Pro. Psychology*, 893 F.3d 1001, 1009 (7th Cir. 2018). The Federal Rules of Civil Procedure do not explicitly address motions *in limine*, but power is inherently vested in district courts in order to ensure just, speedy, and inexpensive dispute resolutions. *See Luce v. United States*, 469 U.S. 38, 41 n.4 (1984) ("Although the Federal Rules of Evidence do not explicitly authorize *in limine* rulings, the practice has developed pursuant to the district court's inherent authority to manage the course of trials."). "Motions *in*

limine are well-established devices that streamline trials and settle evidentiary disputes in advance, so that trials are not interrupted mid-course for the consideration of lengthy and complex evidentiary issues.” *United States v. Tokash*, 282 F.3d 962, 968 (7th Cir. 2002). During trial, however, the presiding judge “is free, in the exercise of sound judicial discretion, to alter a previous *in limine* ruling.” *Luce*, 469 U.S. at 41–42; *see also Ohler v. U.S.*, 529 U.S. 753, 758 n.3 (2000) (“[I]n *limine* rulings are not binding on the trial judge, and the judge may always change [her] mind during the course of a trial.”).

BACKGROUND

This Court presumes familiarity with its summary judgment opinion. [281]. Nonetheless, because some of the issues discussed in that opinion touch on the parties’ motions in *limine*, this Court briefly revisits those facts.

Defendant received a warning letter from the U.S. Food and Drug Administration (FDA) on October 11, 2012 identifying six separate violations of Defendant’s Hudson, New Hampshire facility. [281] at 14. The letter stated that the FDA completed an inspection of the facility from July 31 to September 7, 2012, and the inspection revealed that Defendant’s medical devices were “adulterated” as defined in Section 501(h) of the Food, Drug, and Cosmetic Act (FDCA). *Id.* Relevant here, one of those violations accused Defendant with “Failure to validate with a high degree of assurance, a process whose results cannot be fully verified by subsequent inspection and test. . . . For example, you have not adequately validated your current Ethylene Oxide (ETO) sterilization process that is used to sterilize all thirty-nine (39)

of your medical devices.” *Id.* at 15. The FDA required Defendant to provide “documentation of successful validation once completed” and to “conduct a successful validation of your sterilization operations to demonstrate product sterility.” *Id.*

Defendant’s sterilization plan became effective in May 2013. *Id.*

On December 10, 2013, Plaintiff underwent right-side inguinal hernia repair at Marshfield Clinic in Wisconsin. *Id.* at 4. During the surgery, Plaintiff’s physician implanted a Pro-Lite mesh product manufactured by Defendant in March 2013. *Id.* at 15 n.6.

ANALYSIS

I. Defendant’s Motion in Limine No. 1

Defendant moves to exclude evidence and argument of a consent decree between it and the federal government. [301]. In February 2015, the United States and Defendant, among other entities, reached a consent decree that a New Hampshire federal court entered on February 3, 2015. [301-1]. The consent decree shut down Defendant’s manufacturing facility in Hudson, New Hampshire and ordered Defendant to come into compliance with the FDCA’s manufacturing regulations. *Id.*

Plaintiff seeks to admit the complaint and the consent decree from the New Hampshire federal court. [318] at 5. Apparently conceding that the complaint would otherwise be hearsay, he argues that the complaint nonetheless falls under the public records exception to the rule against hearsay, see [318] at 5 n.2, which admits a “record or statement of a public office” if it sets out in a civil case “factual findings

from a legally authorized investigation” and the “opponent does not show that the source of information or other circumstances indicate a lack of trustworthiness.” Fed. R. Evid. 803(8). But obviously, a complaint contains mere allegations, not factual findings. *See Jordan v. Binns*, 712 F.3d 1123, 1133 (7th Cir. 2013) (emphasizing that the exception requires “factual findings”) (quoting *Beech Aircraft Corp. v. Rainey*, 488 U.S. 153, 170 (1988)); *see also Gumwood HP Shopping Partners, L.P. v. Simon Prop. Grp., Inc.*, No. 3:11-CV-268 JD, 2016 WL 10706086, at *5 (N.D. Ind. Oct. 28, 2016) (noting that “the allegations in the complaint are allegations, not findings”). The complaint thus is not admissible under the public records exception.

As to the consent decree, Plaintiff contend that it constitutes non-hearsay evidence as a “statement of a party opponent” under Rule 801(d)(2). [318] at 5 n.2. This Court disagrees. A consent decree is “a judicial act,” *Perkins v. City of Chicago Heights*, 47 F.3d 212, 216 (7th Cir. 1995), and court rulings “are not statements of a party,” *Bowers v. City of Philadelphia*, No. CIV.A. 06-3229, 2008 WL 5234318, at *6 (E.D. Pa. Dec. 12, 2008). Indeed, civil “judgments are . . . not to be usable in subsequent proceedings as evidence of the facts underlying the judgment; for as to those facts, the judgment is hearsay.” *Greycas, Inc. v. Proud*, 826 F.2d 1560, 1567 (7th Cir. 1987). Moreover, “consent orders are considered settlements for purposes of Rule 408.” *Saccameno v. Ocwen Loan Servicing, LLC*, No. 15 C 1164, 2018 WL 10609658, at *2 (N.D. Ill. Apr. 2, 2018). Thus, courts in this district have held that consent decrees as inadmissible under Federal Rule of Evidence 408 when offered to “prove the truth of the matters asserted in the consent decree or to impeach [a

witness's] credibility.” *Meyer v. Ward*, No. 13 C 3303, 2017 WL 1862626, at *2 (N.D. Ill. May 9, 2017) (collecting cases regarding consent decrees entered with the Securities & Exchange Commission).

For these reasons, this Court **GRANTS** Defendant's Motion in Limine No. 1 and precludes any reference or argument to the complaint and consent decree.

II. Defendant's Motion in Limine No. 3

Defendant moves to exclude evidence and argument regarding a conviction entered by an Italian court in 2017 against Defendant and its former president, Trevor Carlton, for bribing doctors. [303].

Plaintiff asserts he can use evidence of the conviction for impeachment purposes under Federal Rule of Evidence 609. But the Italian appellate court overturned the Italian conviction in 2020, writing that it “acquits the defendants of the remaining crimes respectively ascribed to them.” [303-2] at 2. It is “elementary that once a conviction has been reversed, it cannot be used to impeach the accused” until Rule 609. *United States v. Russell*, 221 F.3d 615, 620 n.6 (4th Cir. 2000) (citing *United States v. Empire Packing Co.*, 174 F.2d 16, 20 (7th Cir. 1949)). Plaintiff thus cannot use evidence of the conviction for impeachment purposes.

Nor is the evidence admissible, as Plaintiff argues, under Federal Rule of Evidence 405(b), which provides that “When a person's character or character trait is an essential element of a charge, claim, or defense, the character or trait may also be proved by relevant specific instances of the person's conduct.” Neither Defendant's nor Carlton's character or character trait is an essential element of the claims or

defenses in this case. And in any case, as stated above, the Italian appellate court vacated the conviction, so the (now overturned) conviction has no relevance to Carlton's character.

For these reasons, this Court **GRANTS** Defendant's Motion in Limine No. 3.

III. Defendant's Motion in Limine No. 5

Defendant moves to exclude financial information relating to his foreign parent corporation, Getinge AB, as well as compensation received by Getinge AB and Defendant's employees. [304] at 8.

This Court finds that evidence associated with the financial status of Defendant's parent company and employees is irrelevant where, as here, the parent is not a named party, the parent did not participate in the conduct giving rise to Plaintiff's claims, and Plaintiff has not demonstrated that the corporate veil should be pierced. *See Castrillon v. St. Vincent Hosp. & Health Care Ctr., Inc.*, No. 1:11-CV-430-WTL-DML, 2015 WL 13861963, at *3 (S.D. Ind. May 11, 2015) (excluding as irrelevant the "relationship with and financial status of . . . [a] parent company or its affiliated companies"); *accord In re Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Prod. Liab. Litig.*, No. 2:18-CV-1509, 2021 WL 2646771, at *3 (S.D. Ohio June 28, 2021) ("When courts have considered the wealth of a parent company, the parent corporation was typically a named party or was involved in the events giving rise to the lawsuit.").

This Court also finds evidence of employee compensation irrelevant. Plaintiff claims that it would use evidence of Trevor Carlton's compensation to demonstrate

“the importance of [h]is position” and “his motivation to keep his high-paying job.” [321] at 5. But Plaintiff does not dispute that Carlton left the company in 2015, three years before his deposition and six years before trial. [304] at 13. Evidence of his prior compensation is thus irrelevant to show the purported “importance” of his position and any motivation to “keep his high-paying job.”

For these reasons, this Court **GRANTS** Defendant’s Motion in Limine No. 5.

IV. Defendant’s Motion in Limine No. 6

Defendant moves to preclude evidence or argument regarding the presence or absence of a corporate representative of Atrium. [304] at 13. Plaintiff responds that Defendant will not call any of its key executives at the center of the FDA inspections, including Carlton, to testify in person at trial.

In the Seventh Circuit, the jury is permitted to draw an adverse inference about the testimony of a missing witness only if “that witness is peculiarly within the opposing party’s power to produce.” *Littlefield v. McGuffey*, 954 F.2d 1337, 1346 (7th Cir. 1992). Stated differently, Plaintiff must demonstrate that: “(1) the missing witness was physically available only to the party against whom the inference would be drawn; or (2) the missing witness has a relationship with that party that practically renders the testimony unavailable to that party’s adversary.” *Kaiser v. Monroe Clinic, Inc.*, No. 19-CV-315-JDP, 2020 WL 4364179, at *9 (W.D. Wis. July 30, 2020) (citing Seventh Circuit Civil Pattern Instruction 1.19, Committee Comment). Plaintiff does not make a specific showing that either of these circumstances exists here. Plaintiff argues only specifically that he should be allowed

a missing witness instruction as to Carlton. [321] at 5. But Carlton no longer works for Defendant, and thus, he is not “peculiarly within [Defendant]’s power to produce.” *Littlefield*, 954 F.2d at 1346; *see also, e.g., Reynolds v. Am. Airlines, Inc.*, No. 14 CV 2429 (CLP), 2017 WL 5613115, at *12 (E.D.N.Y. Nov. 21, 2017) (precluding missing witness argument and evidence related to a retired employee of the defendant).

This Court therefore **GRANTS** Defendant’s Motion in Limine No. 6.

V. Defendant’s Motion in Limine No. 8

Defendant moves to preclude evidence and argument that the FDA rejected its sterilization revalidation. [304] at 13. In response, Plaintiff states that he “need not introduce any evidence that FDA rejected Atrium’s revalidation.” [321] at 8. Given Plaintiff’s representation, this Court **GRANTS THIS MOTION AS AGREED**. The parties shall not introduce any evidence or argument suggesting that the FDA rejected Defendants’ sterilization re-validation.

VI. Plaintiff’s Motion in Limine No. 1

Plaintiff moves to exclude expert opinions Defendant disclosed on July 19, 2021 [296], actually disclosed on July 14, 2021, and to strike Defendant’s July 14th expert witness disclosure. [296]. Plaintiff argues that Defendant’s disclosure is untimely because Magistrate Judge Kim set a deadline for Defendant to provide its expert disclosures over two years ago, by June 7, 2019. *Id.* Plaintiff misapprehends Judge Kim’s order.

On March 12, 2019, Magistrate Judge Kim ordered that “Defendant . . . serve its Rule 26(a)(2) *reports* on plaintiff by June 7, 2019.” [148] (emphasis added). The

order only addressed the exchange of expert reports and did not set a deadline for disclosing experts who were not required to prepare a report pursuant to Federal Rule of Civil Procedure 26(a)(2)(E). Federal Rule of Civil Procedure 26(a)(2) distinguishes between retained experts who are required to provide a written report and non-retained experts who are not. Under Rule 26(a)(2)(C), non-retained experts need not provide a report; rather, the party calling the witness must provide a disclosure stating “the subject matter on which the witness is expected to present evidence” and “a summary of the facts and opinions to which the witness is expected to testify.” Under Rule 26(a)(2)(D), absent a court order, such a disclosure must be made “at least 90 days before the date set for trial or for the case to be ready for trial.”

Because this Court never set a deadline for disclosure of non-retained expert witnesses (i.e, experts not required to provide a report), Defendant needed only to disclose the experts ninety days before the start of trial—in this case, by July 15, 2021. On July 14, 2021, the day before the deadline, Defendant disclosed its six non-retained expert witnesses pursuant to Rule 26(a)(2)(C). [296] at 5–9. Thus, its disclosure was timely.

This Court therefore **DENIES** Plaintiff’s Motion in Limine No. 1.

VII. Plaintiff’s Motion in Limine No. 2

Plaintiff moves to exclude any report or testimony of Gerry O’Dell. [297]. Defendant hired O’Dell as a sterilization consultant around 2012 after it received the FDA warning letter. [323] at 1. Neither party has named O’Dell as a witness. *Id.* Instead, Defendant seeks to introduce three letters from O’Dell that it included in

correspondence with the FDA in November 2012 and January 2013; these letters explain the revalidation of Defendant's sterilization process. [323] at 3. Defendant contends that these letters fall under the business records exception to hearsay pursuant to Federal Rule of Evidence 803(6). *Id.* Rule 803(6), the business-records exception "removes the hearsay bar for records kept in the course of a regularly conducted business activity if making the records is a regular practice of that business activity, so long as 'neither the source of information nor the method or circumstances of preparation indicate a lack of trustworthiness.'" *Jordan v. Binns*, 712 F.3d 1123, 1135 (7th Cir. 2013) (quoting Fed. R. Evid. 803(6)).

Defendant includes a business records affidavit from O'Dell stating that the letters were created "in the regular course of business, at the time of the act, transaction, occurrence or event recorded therein, or within a reasonable time thereafter, made by—or from information transmitted by—a person having knowledge of those matters, and were kept in the regular course of business." [323-1] at 2. This suffices to lay a foundation for the documents' admissibility as business records. *See United States v. Bledsoe*, 70 F. App'x 370, 373 (7th Cir. 2003). Notwithstanding, "that certification alone" is insufficient; this Court must ensure that the documents are still "trustworthy" under Rule 803(6). *United States v. Brown*, 822 F.3d 966, 973 (7th Cir. 2016).

In *Jordan v. Binns*, the Seventh Circuit held that the district court abused its discretion by admitting a third-party insurance adjuster's report created after an accident investigation. 712 F.3d at 1136. As the court noted, "documents prepared

with an eye toward litigation raise serious trustworthiness concerns because there is a strong incentive to deceive (namely, avoiding liability).” *Id.* at 1135. The court of appeals relied in part upon a Ninth Circuit decision holding that an audit performed by a third-party accounting firm did not constitute a business record because “it was commissioned only after accounting problems were suspected.” *Id.* at 1136 (quoting *Paddack v. Dave Christensen, Inc.*, 745 F.2d 1254, 1258–69 (9th Cir. 1984)). The Seventh Circuit also explained that “a nonaffiliated investigator may have pecuniary motives to skew a report in favor of the client that hired him, for a damaging report may result in the client looking elsewhere next time around.” *Id.*

This Court finds that O’Dell’s letters lack trustworthiness to qualify them under the business records exception. It is undisputed that Defendant hired O’Dell to look into Defendant’s sterilization practices and prepared her letters *after* knowing of the FDA’s concerns. Plaintiff points to an email from Atrium’s Frank Casamassina to O’Dell from August 2012, in which Casamassina writes:

We have FDA at our Atrium facility in NH. They are challenging our choice of product for worst case challenge. Steris made the choice; we lack the written rationale. We trusted their guidance, which wasn’t necessarily wrong. FDA therefore stated that we may not have confirmed sterility in the field. . . they may also try to implicate infection complaints (surgical mesh, months or years after surgery). . . . We need a strategy on our position.

[297] at 38–39. This email suggests that Defendant hired O’Dell for the very purpose of defending against the government accusations regarding sterilization issues. Moreover, as an outside consultant, O’Dell may have had an incentive to report positive results for Defendant. These circumstances indicate a lack of routineness to

the documents and raise similar trustworthiness concerns that the Seventh Circuit encountered in *Jordan*. *See also* Fed. R. Evid. 803(6) advisory committee's note ("Absence of routineness raises lack of motivation to be accurate.").

This Court therefore **GRANTS** Plaintiff's Motion in Limine No. 2.

CONCLUSION

For the stated reasons, this Court grants Defendant's motion in limine No.1 [301]; grants Defendant's motion in limine No. 3 [303]; grants Defendant's motions in limine Nos. 5, 6, and 8 [304]; denies Plaintiff's motion in limine No. 1 [296]; and grants Plaintiff's motion in limine No. 2 [297]. This Court reserves ruling on the remaining motions in limine.

E N T E R:

Dated: September 30, 2021

A handwritten signature in black ink, reading "Mary M Rowland". The signature is written in a cursive, flowing style. The first name "Mary" is written in a larger, more prominent script, followed by "M" and "Rowland".

MARY M. ROWLAND
United States District Judge